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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/889,017	07/07/97	SHEHADA	P07-38135

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EXAMINER	
ISRAEL, A	
ART UNIT	PAPER NUMBER
2878	

DATE MAILED: 08/16/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/889,017

Applicant(s)
Shehada et al.

Examiner
Andrew Israel

Group Art Unit
2878



☒ Responsive to communication(s) filed on Jun 10, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-42 and 48-60 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) 8-10, 35, 40, 42, 49, 51, 59, and 60 is/are allowed.

☒ Claim(s) 1-7, 11-24, 29-34, 36-39, 41, 48, 50, and 52-58 is/are rejected.

☒ Claim(s) 25-28 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Examiner's Response to Amendment

The amendment filed June 10, 1999 has been entered in full.

Due to the Information Disclosure Statement filed by Applicant with the amendment of June 7, 1999, new art rejections were made based on the WO 97/08538 document supplied.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

2. Claims 1, 2, 4-7, 11, 18, 30, 31, 33, 34, 39, 41, 48, 50, and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Zuckerman (U.S. Patent # 5,495,850). Concerning claims 1, 2, 4-7, 11, 18, 30, 31, 33, 34, 39, 41, 48, 50, and 52, Zuckerman discloses in Figure 3 and column 10, lines 1-48, a spectroscopic method and device for determining a physiological characteristic of a biological sample (or hemoglobin concentration, see col. 2, line 41), comprising: irradiating a living tissue (or biological) sample (col.8, line 17) with substantially

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monochromatic radiation through waveguide (or optical fiber bundle) **66** from source **52** to induce fluorescence (col. 8, lines 17-20) in the sample; monitoring a first portion of the modulated return fluorescence at a first distance from the sample with a first sensor **88A**; monitoring a second portion of the return fluorescence at a second distance from the sample with a second sensor **88B**; and processing the first and second portions of the return radiation with microprocessor **90** using a predictive model (see abstract). The oxygen concentration (a physiological property) of the sample is measured by this method.

3. Claims 1-7, 11-22, 30, 31, 36-38, and 53-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Alfano et al (U.S. Patent # 5,635,402). Alfano discloses in Figure 2 and column 4, lines 20-32 and column 5, lines 36-68, an apparatus and method for determining a physiological or pathological (malignancy) property of a living tissue sample (or sample volume), comprising a monochromatic laser source **43** (see col. 5, line 38 and col. 4, line 20); a first waveguide (optical fiber bundle) **B** disposed a first distance from a biological sample **S** to transmit radiation to the sample and induce fluorescence of the sample; a first sensor **59** for determining the intensity of the first portion of modulated return light; a second waveguide (optical fiber bundle) **53** disposed at a second distance for receiving a second portion of return light; a second sensor **61** for determining the intensity of the second portion of return light; and a processor **52** adapted to determine a physiological property of the biological material.

4. Claims 1, 2, 4-7, 11-17, 19-22, 30, 36-38, 52-54, and 56-58 rejected under 35 U.S.C. 102(a) as being anticipated by Sevick-Muraca et al (International Patent Application WO

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97/08538). Regarding claims 1, 2, 4-7, 11-17, 19-22, 30, 36-38, 52-54, and 56-58, Sevick-Muraca discloses in Figure 1 and page 7, line 10 through page 8, line 13, an apparatus for analyzing a sample, comprising: a monochromatic light source **120** adapted to emit radiation that is directed at a biological sample **100** to produce return radiation (or fluorescence) from the biological sample **100**, wherein the return radiation is modulated by the sample; a first waveguide (or optical fiber) **123** disposed a first distance from the sample to transmit the excitation light from the light source to the biological sample; a first sensor **148** adapted to monitor the return radiation at a first distance from the sample; a second waveguide (or optical fiber) **143** disposed at a second distance from the sample adapted to collect a second portion of the return light; a second sensor **148** (contains one or more sensors, see pg. 7, line 23) adapted to monitor the return radiation at a second distance from the sample; and a processor associated with the first and second sensor and adapted to process signals from the sensors to determine various sample characteristics.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al (U.S. Patent # 5,635,402). Alfano does not disclose a method where first and second radiation signals are measured consecutively or simultaneously. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to make these measurements consecutively and simultaneously depending on the nature of the experiment being performed.

7. Claims 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zuckerman (U.S. Patent # 5,495,850) in view of Powers (U.S. Patent # 5,760,406). Zuckerman does disclose a method for determining a physiological property (oxygen concentration) of a sample. Zuckerman does not disclose a method for the measurement of the intrinsic fluorescence of a sample. Regarding claims 29-34, Powers discloses in Figure 1 and column 4, lines 23-65, a method and apparatus for determine the intrinsic fluorescence of a sample. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of

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Zuckerman to measure the intrinsic fluorescence of a sample in order to gain more accurate information about the physiological properties of the sample.

Allowable Subject Matter

8. Claims 8-10, 35, 40, 42, 49, 51, 59, and 60 are allowed.
9. Claims 25-28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
10. The following is a statement of reasons for the indication of allowable subject matter: regarding claims 8-10, 35, 40, 42, 49, 51, 59, and 60, the reasons for allowance set forth in the previous Office Action will suffice; claim 25-28 are allowable because Zuckerman or Sevick-Muraca makes no disclosure of attenuation, transmittance, or absorption measurements of a sample.

Response to Arguments

11. Applicant's arguments filed June 7, 1999 have been fully considered but they are not persuasive. Zuckerman, Alfano, and now Sevick-Muraca disclose monitoring return radiation from a sample at a first and second distance. No other specific limitation is claimed regarding the two distances relative to the source, sensors, or sample. For example, there is no requirement

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that the two distances are even different. Therefore, Zuckerman, Alfano, and Sevick-Muraca adequately disclose the claimed invention as stated in this Office Action.

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew Israel whose telephone number is (703) 305-0382.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 2800 receptionist whose telephone number is (703) 308-0956.

Papers related to Technology Center 2800 applications **only** may be submitted to Technology Center 2800 by facsimile transmission. Any transmission not to be considered an official response must be clearly marked "DRAFT." The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 34-35 (November 15, 1988). The Fax number for Group Art Unit 2878 is (703) 308-7722 or (703) 308-7724.

AI

AI
August 12, 1999

Constantine Hanna
CONSTANTINE HANNAHER
PRIMARY EXAMINER
GROUP ART UNIT 2878